ORAL

TCT-100

EVEREST II Randomized Clinical Trial: A Critical Assessment of Anatomical Predictors of de novo Mitral Valve Replacement or following the MitraClip Procedure

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Background: EVEREST II is a prospective, multi-center, randomized controlled trial designed to compare the safety and effectiveness of the MitraClip System with mitral valve surgery in the treatment of mitral regurgitation (MR). The study was designed to demonstrate the safety and effectiveness of the MitraClip device compared to surgery. Patients were randomized to treatment with the MitraClip device (Device) or mitral valve repair or replacement surgery (Control). Patients randomized to the Device group could convert to MV Surgery if clinically necessary. A critical analysis was performed to determine patient characteristics which predict the likelihood of de novo MV replacement in patients randomized to Control, and in patients referred to surgery following the MitraClip procedure.
Methods: 279 patients were enrolled at 37 sites in North America and randomized 2:1 (Device vs. Control). Eighty Control patients underwent MV Surgery and 37 Device patients underwent MV Surgery during the first year following the MitraClip procedure. We hypothesized that the decision to replace or repair the valve in either the Control or Device Group was related to specific pathological characteristics. A composite score of specific factors including etiology, presence of anterior/bileaflet disease, leaflet/annular calcification, number of scallops with pathology, and endocarditis was determined. Each factor was counted as one. A mean score per patient was determined. In addition, age, and surgeon experience was assessed. Subsequently, a logistic regression model was used to predict repair or replacement. Details and results of this analysis will be presented.
Results: In the Control group 11 patients had MV Replacement with a mean pathology score of 1.12. In the Device group, patients who underwent MV Replacement following the MitraClip procedure had a mean score of 0.91. In contrast, patients who underwent MV Repair in either the Control group or the Device Group had mean predictive composite scores of 0.55, and 0.52, respectively. Patients were slightly older in the MV Replacement group. Surgeon experience, defined as number of surgeries performed annually, was greater in the MV Replacement arm (67.1 cases/year vs 59.2 cases/yr for Repair).
Conclusion: Patient anatomy and pathology are the primary drivers in the decision to replace versus repair the mitral valve. A detailed analysis of the anatomical and pathological characteristics contributing to MV Replacement versus MV repair in the EVEREST II Randomized Clinical Trial will be presented.

TCT-101

EVEREST II Randomized Clinical Trial: Significant Reverse Left Ventricular Remodeling One Year following MV Surgery and MitraClip Therapy

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EVEREST II is a prospective, multi-center, randomized controlled trial designed to compare the safety and effectiveness of the MitraClip System with mitral valve surgery in the treatment of mitral regurgitation (MR). Patients were randomized to treatment with the MitraClip device (Device) or mitral valve repair or replacement surgery (Control). Measures of 12 month effectiveness included an analysis of echocardiographic determinants of left ventricular (LV) function.
Methods: 279 patients were enrolled at 37 sites in North America and randomized 2:1 (Device vs. Control). Echocardiographic measures of LV function were determined by the Echocardiographic Core Lab at UCSF at baseline, discharge, 30days, 6, and 12 months for all patients. Measured LV parameters include LV end diastolic volume, LV end systolic volume, LV internal diastolic diameter, LV internal systolic diameter, and LV ejection fraction. Calculated parameters of LV function include cardiac output (CO), and forward stroke volume (FSV). Additionally, septal-lateral annular dimensions were measured at follow-up in patients who underwent the MitraClip procedure.
Results: Significant reverse LV remodeling at 12 months was observed following successful MitraClip Therapy, defined as acute procedural success (MR≤2+ at discharge), and following MV surgery Twelve month matched LV remodeling data for both therapies is presented in Table 1. A detailed discussion of these data and other LV function data will be presented.
Table:

	MitraClip Procedure			Mitral Valve Surgery		
	Baseline	12 Months	P value	Baseline	12 Months	P value
LVEDV	154.3±35	133±33.8	<0.0001	161.1±46.6	120.9±44.3	<0.0001
LVESV	61.7±22.6	57.3±23.8	0.0005	61.4±28.1	56.2±31.4	0.0255
LVIDd	5.5±0.6	5.1±0.7	<0.0001	5.4±0.7	4.8±0.7	<0.0001
LVIDs	3.6±0.9	3.5±0.8	0.0564	3.3±0.7	3.3±0.8	0.4785

Conclusion: Significant reverse LV remodeling occurred one year following MV surgery and MitraClip treatment. A detailed analysis of the LV function data from the EVEREST II Randomized Clinical Trial will be presented.

TCT-102

Transapical Beating Heart Mitral Valve Repair With Implantation Of Neo-Chordae - Initial Clinical Experience

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Background: Mitral regurgitation (MR) due to mitral valve (MV) leaflet prolapse is treated with chordal replacement as a standard open heart surgical procedure. Transapical beating heart MV repair based on the concept of chordal replacement has been recently developed as a method to re-suspend the prolapsing leaflet segment. We herein present the initial clinical experience with this novel technique.
Methods: Patients with severe MR (grade 3+ or 4+) due to isolated posterior leaflet prolapse with or without chordae rupture were selected for the procedure. The Neochord DS1000 device (Neochord Inc., Minnetonka, MN, USA) was used to implant polytetrafluoroethylene sutures (Gore-Tex, W. L. Gore & Assoc., Flagstaff, AZ, USA) on the beating heart. Transapical access to the MV was performed through a left lateral mini-thoracotomy (5 cm). The procedure was performed under 3D-transesophageal echocardiographic (TEE) guidance. Institutional ethics committee approval and written informed consent was obtained.
Results: A total of four patients were treated at our institution from March to May 2010. Acute procedural success with elimination of MR (grade 0 in 3 patients, trace to 1+ MR in 1 patient) was achieved in all patients. A total of three Gore-Tex sutures were implanted to the respective prolapsing segment of the posterior leaflet in each patient. The proper suture length was determined with TEE guidance during normal physiological stress (i.e. beating heart without cardiopulmonary bypass). After evaluation of the final repair result the sutures were subsequently secured to the left ventricular apex. Total operative time was 112 +/- 9 minutes. Fast track anaesthesia concept was applied in all patients with a mean postoperative intubation time of 53 +/- 31 minutes. Intraoperative and postoperative course was uneventful in all patients with no adverse events. Pre-discharge echocardiographic control showed no or trace MR in three patients and grade 1+ MR in one patient.
Conclusions: Our initial clinical experience shows that transapical beating heart MV repair with implantation of neo-chordae is feasible and safe for patients with isolated posterior leaflet prolapse. Further evaluation is needed.

TCT-103

Safety and Efficacy Comparison Between Implanted and Non-Implanted Patients in the TITAN™ Trial using the CARILLON® Mitral Contour System™ to Treat Functional Mitral Regurgitation

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Background: Percutaneous techniques are being developed to treat functional mitral regurgitation (FMR). The TITAN™ trial evaluated the safety of the coronary sinus based CARILLON® XE2 device and compared functional measures between implanted and non-implanted patients.
Methods: Heart failure patients with moderate to severe FMR, LVEF<40%, and 6 minute walk distance (6MWD) 150-450 meters were enrolled in the trial. Peri-procedural reduction in FMR and confirmation of unaltered coronary flow were prerequisites to permanent implantation (n=36). Non-implanted patients (e.g., device recaptured) served as a non-randomized, non-blinded control (n=17). The primary safety endpoint was the MAEs rate at 1 month. Secondary endpoints at 1, 6, and 12 months included echo core lab derived quantification of FMR and LV Dimensions, NYHA Class, 6MWD, and QOL measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ).
Results: At baseline, 94% of patients were NYHA III, EF was 28.4%, and LVEDD was 70mm. The MAE rate at 30-days for all 53 attempted patients was 1.9%. Reductions in 4 quantitative FMR measures ranged from 32-43% at 6 months for implanted patients. LVESV was reduced from 164±64 (baseline) to 142±52 (6 months) (p<0.01).
Table: Functional Changes (mean±SD, P value by ANOVA)

	6MWD (m)			NYHA Class			KCCQ		
	Baseline	6 mo	12 mo	Baseline	6 mo	12 mo	Baseline	6 mo	12 mo
Implanted (n=36)	302 ±74	436 ±208	427 ±193	3.06 ±0.2	2.07 ±0.7	2.14 ±0.8	43 ±18	64 ±23	63 ±27
	P=0.0036			P<0.0001			P=0.00012		
Non-Implanted (n=17)	338 ±83	322 ±105	330 ±139	2.9 ±0.2	2.7 ±0.7	2.4 ±0.5	40 ±19	50 ±22	45 ±12
	P=0.915			P=0.135			P=0.655		

Final 12 month TITAN results will be presented.
Conclusion: Percutaneous treatment of FMR with the CARILLON® Mitral Contour System™ was associated with reduction in FMR in the TITAN trial, and a significantly greater improvement in functional parameters.

TCT-104

Impact of Crossing Coronary Arteries with a Coronary Sinus Based Device in the TITAN Study

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The Carillon® Mitral Contour System™ (CMCS) is a coronary sinus based device designed to treat functional mitral regurgitation (MR). The circumflex & rarely the distal RCA also course in the posterior AV groove. Prior studies have shown a high incidence of coronary artery crossing (ca cross) with the CMCS, but with relatively infrequent need to abort the procedure due to coronary artery compression (cac). The TITAN study is a safety and feasibility study of the XE2 version of the CMCS. This study assessed the clinical impact of ca cross in TITAN.

Methods: Pts enrolled in TITAN had symptomatic CHF, FMR ≥2+, enlarged LV's and low EF's. After placement of CMCS, cor angio was done immediately to look for cac. If no cac, and there was an improvement in MR the device was released, otherwise it was recaptured. Cine films were reviewed for the presence or absence of ca cross. Patients who had ca cross were compared with patients without ca cross for clinical and echo changes at 6 month follow-up.
Results: 53 pts were enrolled in Titan, with 36 receiving implants. In 34 pts (64%) a coronary artery was crossed. Of the 17 pts without implants 8 pts had the device removed at least in part due to cac, thus 15% of implants were limited by cac. No patient had an MI within 30 days of the procedure. 7 pts had chest pain with FU to one year, 12% w crossing vs 16% without (NS). 5 pts had cor angios, with none showing CMCS-related coronary artery compromise. 11 pts died with FU (includes non-implanted pts): 18% w ca cross vs 26% wo (NS). No echo or clinical differences were seen in FU between those w vs wo ca cross (Table), except for reduced MR at 6 month FU in patients with coronary artery crossing.

Echo and Clinical Comparisons between patients with a crossed coronary artery and those without

	MR Baseline	MR 1 mo	MR 6 mo	NYHA Baseline	NYHA 1 mo	NYHA 6 mo	6 MWT Baseline	6 MWT 1 mo	6 MWT 6 mo
+ ca Cross	2.7±0.7	1.9±1.0	1.1±1.1	3.1±0.2	1.9±0.6	1.9±0.7	312±77	414±145	473±247
- ca Cross	2.9±0.5	2.1±0.9	2.2±0.6*	3.1±0.2	2.2±0.8	2.2±0.6	292±70	386±160	395±157
*P<0.05 compared with + ca cross									

Conclusions: Similar to the findings in AMADEUS, coronary artery crossing is common when using the CMCS, but infrequently limits successful deployment, and does not appear to have any impact on medium-term safety or efficacy.

Plenary Session XVIII
The Best of the Best TCT 2010 Abstracts
Main Arena
Friday, September 24, 2010, 2:50 pm – 3:30 pm
(Abstract Nos 105-107)

TCT-105

Three-year Follow-up Of The Syntax Trial: Optimal Revascularization Strategy In Patients With Left Main Disease

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Background: Percutaneous coronary intervention (PCI) is an increasingly common revascularization strategy for patients (pts) with left main (LM) stenosis. Recently, ACC/AHA PCI guidelines upgraded unprotected LM PCI to a class IIb indication. Long-term follow-up data in LM pts have been limited. This analysis will examine 3-year outcomes of LM pts in the SYNTAX trial.
Methods: SYNTAX randomized pts with *de novo* 3 vessel (3VD) and/or LM disease to PCI with TAXUS Express stents or coronary artery bypass surgery (CABG) if suitable for equivalent revascularization using either treatment. Analysis of the LM cohort was prespecified and sufficiently powered.
Results: Two-year MACCE (major adverse cardiac and cerebrovascular events) was similar in LM PCI and CABG-treated pts (CABG 19.3% vs PCI 22.9%) as was death/stroke/MI (11.8% vs 10.2%; Table). Stroke was significantly increased in the CABG group (2.4% vs 1.2%, *P*=0.01) and repeat revascularization was increased in the PCI arm (10.4% vs 17.3%, *P*=0.01) at 2 years (Table). MACCE was similar between groups in pts with lower SYNTAX Scores (0-32: 20.5% vs 18.3%, *P*=0.48) but significantly increased in PCI pts with high scores (33+: 17.8% vs 29.7%, *P*=0.02). Outcomes at 3-years will be available and presented for the first time.

Adverse Event Rates in the LM cohort at 2 years						
		CABG	PCI		CABG	PCI
2-year Rates	MACCE	19.3	22.9	Stroke	3.7	0.9*
	Death/Stroke/MI	11.8	10.2	MI	4.1	5.5
	Death	6.2	5.6	Repeat Revascularization	10.4	17.3*

MACCE: All-cause death, stroke, MI, repeat revascularization. Time-to-event rates at 2 years. *P<0.05 from log-rank or chi-square test.
Conclusions: Positive outcomes from SYNTAX and other recent studies of LM disease suggest PCI using drug-eluting stents may be as effective but less invasive than CABG in certain subsets of pts. The three year data to be presented will continue to clarify the role of PCI relative to CABG for the treatment of patients with LM disease.

TCT-106

Quality of Life for Patients Undergoing Percutaneous Vascular Intervention for Claudication vs Critical Limb Ischemia, Insights from the Blue Cross Blue Shield of Michigan Cardiovascular Consortium

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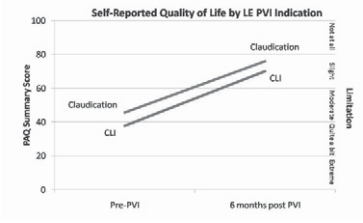
Background: Lower extremity percutaneous vascular interventions (LE PVIs) are generally performed to improve the quality of life (QoL) of patients with symptomatic peripheral arterial disease (PAD). We sought to evaluate and compare the baseline and 6 month post-intervention QoL in patients who underwent PVI for either claudication or critical limb ischemia (CLI).
Methods: QoL data were assessed at baseline and 6 months using the Peripheral Arterial Questionnaire (PAQ) for 1667 PVI patients in a multicenter, multidisciplinary regional consortium. Analysis of variance was employed to compare temporal change in QoL based on indication for LE PVI (Claudication vs CLI).
Results: (See graph). There were 1037 patients in the claudication group and 630 patients in the CLI cohort. The mean age was 68 (± 11) years, and did not differ between groups. More CLI patients were women (47 vs 41%; p<0.02). Insulin requiring diabetes was more common in the CLI cohort (31 vs 15%; p<0.0001), as was dialysis (5.6 vs 1.7%; p<0.0001). At baseline, patients with CLI reported lower overall QoL than patients with claudication (p<0.0001). At 6 months, the claudication indication for PVI patients reported a better QoL than CLI indication patients (p<0.0001). The improvement in QoL from baseline to 6 months post PVI was equivalent in both groups (p=0.2).



Conclusions: The QoL of all patients referred for LE PVI is severely impaired, particularly in those patients with CLI. LE PVI for patients with either claudication or CLI is associated with equivalent and dramatic improvement in QoL that is sustained for at least 6 months post intervention.

TCT-107

EVEREST II Randomized Clinical Trial: Clinical Benefit by MR Grade in Patients One Year following Successful MitraClip Therapy

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Background: EVEREST II is a prospective, multi-center, randomized controlled trial designed to compare the safety and effectiveness of the MitraClip System with mitral valve surgery in the treatment of mitral regurgitation (MR). Measures of 12 month clinical benefit, defined as improvements in LV function and symptomatic improvement, were evaluated for the Device Group and Control Group, and have been previously reported. Observed clinical benefit by 12 month MR grade has not been reported. These data are important to understanding the therapeutic potential of the MitraClip procedure.
Methods: Twelve month clinical benefit observed in patients with ongoing clinical success (defined as acute procedural success with MR ≤2+ at discharge and continued MR reduction ≤2+ at 12 months) in the Device group is reported. Measures of clinical benefit include echocardiographic measures of LV function, NYHA functional class, and Quality of Life scores. Additional analyses of clinical benefit are reported for Device group patients stratified by 12 month MR grade. Comparisons will be made with the overall Device Group and Control Group.
Results: Significant improvement in LV function, NYHA Functional Class, and Quality of Life scores was observed for all Device patients with ongoing success (MR≤2+ at 12 months). Patients with MR reduced to 1+, 1+ to 2+, or 2+ at 12months demonstrated marked clinical benefit, with significant improvements noted from baseline to 12 months. A detailed analysis of these data will be presented.

12 Month MR Grade	Duration	LVEDV (ml)	LVESV (ml)	NYHA Class I/II (%)	PCS Score	MCS Score
MR≤1+ (n=41)	Baseline	156.3±35.5	66.1±24.2	40	40.6±9.3	46.6±11.2
	12 months	126.5±32.9	55.6±24.7	100	44.8±8.3	53.3±7.6
MR 1+ to 2+ (n=14)	Baseline	144.5±36.0	56.1±19.4	78.6	43.7±9.1	49.5±10.4
	12 months	134.5±28.5	58.0±21.8	100	48.9±9.7	52.6±4.8
MR = 2+ (n=39)	Baseline	152.4±34.3	58.6±21.7	48.7	40.6±10.4	46.9±11.7
	12 months	134.4±33.8	57.2±22.5	94.9	45.9±10.1	53.7±7.5

*Remaining patients: 6 died, 9 underwent surgery, 6 withdrew or missed a 12 month visit or echo, 22 had MR > 2+
Conclusion: Significant measures of clinical benefit are observed one year following successful MitraClip therapy. A detailed analysis of the clinical data based on 12 month MR grade from the EVEREST II Randomized Clinical Trial will be presented.

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